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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,806	03/31/2004	Constantin Cope	8627/487 (PA-5391RFB)	7536
27879 7590 02/11/2008 INDIANAPOLIS OFFICE 27879 BRINKS HOFER GILSON & LIONE ONE INDIANA SQUARE, SUITE 1600 INDIANAPOLIS, IN 46204-2033			EXAMINER BOUCHELLE, LAURA A	
			ART UNIT 3763	PAPER NUMBER
			NOTIFICATION DATE 02/11/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentofficeactions@brinkshofer.com
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Office Action Summary

Application No.

10/813,806

Applicant(s)

COPE ET AL.

Examiner

LAURA A. BOUCHELLE

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-14, 16-24 and 29-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-14, 16-24 and 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 2, 7-10, 14, 16-18, 21-24, 29, 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Osypka et al (US 2003/0216771). Osypka discloses a vascular introducer assembly with a hemostatic seal comprising a needle 18, a needle hub 20, a needle hub attachment assembly 22, and a hemostatic segment comprising a guidewire inserter 28. The distal end of the hemostatic segment tapers to an end hole having a diameter substantially the same as the guidewire 86. See Fig. 5. The device comprises two elastomeric valves 58, 80. The needle hub and the hub attachment assembly are connected through a leak free threaded engagement.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 3, 4, 12, 19, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka in view of Raulerson et al (US 6551281). Claims 3, 4, 19, 32 differ from Osypka in calling for the hemostatic segment to include a guidewire holder that is preloaded with a guidewire. Claim 12 calls for the holder to fasten the guidewire in a loop. Raulerson teaches a guidewire advancer comprising a guidewire holder 24 that is preloaded with a guidewire 21 fastened in a loop so that the guidewire can be easily manipulated by the user and remain sterile

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while it is inserted into the patient through the introducer device 30. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the device of Osypka a preloaded guidewire holder as taught by Raulerson so that the guidewire can be easily manipulated by the user and remain sterile while it is inserted into the patient through the introducer device.

5. Claims 11, 20, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka in view of Padilla et al (US 5984895). Claims 11, 20, 31 differ from Osypka in calling for the needle hub attachment assembly to be transparent. Padilla teaches a vascular blood flashback containment device comprising a hub attachment assembly 38 that is transparent to allow for visualization of blood contained in that segment (Col. 6, lines 12-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Osypka to include a transparent portion as taught by Padilla to allow for visualization of blood contained in the hub attachment area.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka. Claim 13 differs from Osypka in calling for a luer lock connection. At the time the invention was made, it would have been an obvious matter of design choice to use a luer lock connection. Applicant has not disclosed that having a luer lock serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect Osypka and applicant's invention to perform equally well with either a threaded connection or a luer lock because both are well known methods of forming fluid tight seals. Therefore, it would have been prima facie

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obvious to modify Osypka to obtain the invention as specified in claim 13 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

Response to Arguments

7. Applicant's arguments filed 8/15/07 have been fully considered but they are not persuasive.

8. Applicant argues that Osypka does not disclose a needle for percutaneous entry. The examiner disagrees. The language of claim 1 reads, "a needle for percutaneous entry...", percutaneous meaning through the skin. The needle 18 of Osypka is inserted through the skin. The examiner interprets the language to mean that the needle must traverse the skin, not that the needle is necessarily used to pierce the skin.

9. Applicant argues that Osypka does not teach a chamber for receiving body fluid. The examiner points applicant to Fig. 9 of the Osypka disclosure. This figure shows fluid 30 entering lumen distally of the hub attachment assembly 22. The fluid flow is contained by seal 58, and thereby forming a chamber distal of the seal where fluid is received.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
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